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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/817,647	04/02/2004	Linda S. Powers	13368.0002	3408

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K. S. Cornaby
Suite 1500
170 South Main Street
Salt Lake City, UT 84101

EXAMINER	
BARNHART, LORA ELIZABETH	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 12/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/817,647	POWERS ET AL.	
	Examiner	Art Unit	
	Lora E. Barnhart	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 November 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) *4-11* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/2/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I, claims 1-3, in the reply filed on 11/8/05 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 4-11 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the above reply. Examination will commence on claims 1-3 ONLY.

Specification

The disclosure is objected to because of the following informalities: Table I (at page 14) is labeled "Excitation and Emission Ranges for Microbial Fluorophores", but no microbes are recited. The examiner suggests that Table I be retitled "Excitation and Emission Ranges for Body Fluids" or similar. Appropriate correction is required.

Priority

The examiner acknowledges that this application is a continuation-in-part of application 10/054,491, now U.S. Patent 6,750,006, but notes for the record that the '006 patent is drawn specifically to detecting and enumerating microbial contamination. The '006 patent does not provide guidance for detecting or enumerating any biological material other than microbes, their spores, and some of their toxins (Table I; column 3, lines 4-39).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for detecting a few fluids and distinguishing them from each other using a few criteria, does not reasonably provide enablement for detecting every biological material and distinguishing it from every other material. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands*, 858 F.2d 731, 737, 8 USPQd 1400, 1404 (Fed. Cir. 1988) (a) the breadth of the claims; (b) the nature of the invention; (c) the state of the prior art; (d) the level of one of ordinary skill; (e) the level of predictability in the art; (f) the amount of direction provided by the inventor; (g) the existence of working examples; and (h) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. While all of these factors are considered, a sufficient number are discussed below so as to create a *prima facie* case.

The claims are drawn (in the examiner's interpretation; see below rejections under 35 U.S.C. § 112, second paragraph) to a method for detecting biological material and distinguishing it from other biological material comprising exciting an intrinsic

fluorophore within the material, detecting the intensity of various emission signals, performing various calculations, and determining the amount of material and distinguishing it from other material. The specification provides limited guidance for each aspect of the invention.

The specification is enabling for biological materials that have intrinsic fluorescence (*i.e.*, inherently comprise molecules that fluoresce when irradiated with electromagnetic radiation), but provides no guidance for biological materials that do not have intrinsic fluorescence. Water, for example, is certainly a biological material, as it is essential to life on earth; pure water, however, does not fluoresce under any conditions. The specification fails to be enabling for a method for the detection of biological materials that, like water, have no property of intrinsic fluorescence.

Even if the claims are interpreted more narrowly as being drawn to detecting and distinguishing biological materials **known to possess intrinsic fluorescence**, the specification still fails to enable the entire invention as claimed. Table I (page 14) provides emission profiles for a few biological materials, namely skin oil, semen, blood, urine, and saliva. The specification does not point out, however, the origin of these materials (*e.g.* mammal vs. reptile, human vs. mouse) and, as such, does not provide sufficient guidance for distinguishing, for example, human urine from mouse urine without undue experimentation. Even if human urine were found to have a distinct emission profile compared to mouse urine, the specification does not enable a method for distinguishing between, for example, the urine of two different humans, or between the urine of a healthy human and that of the same human with a cold.

In addition, Table I provides emission profiles for only five biological materials; the specification is silent as to the emission profiles of other similar materials (for example, mucus, sputum, or pus) and provides no guidance for a scenario in which one of these materials has an emission profile identical to one of the five exemplified materials. It is not clear how two materials could be distinguished from each other if they have identical emission profiles. In short, the scope of the term "biological material" is broader than the specification reasonably enables.

Even if it assumed *arguendo* that the claims are drawn to biological materials that possess an intrinsic fluorescence, and that the intrinsic fluorescence profile of each biological material is distinct from every other profile, the specification still fails to be enabling for the method as claimed. The specification does not detail any algorithm that should be used for step (d), nor does it provide guidance for determining the amount of material as in step (e). There is no evidence within the specification that the claimed method is quantitative, or that the intensity of emitted radiation is directly proportional to the amount of every possible biological material. The specification discloses at page 15 that the amount of radiation can be quantified, but no guidance is provided for the correlation of a given intensity at a given wavelength with a given amount of a given biological material.

Finally, the specification is not fully enabling even for the exemplified biological materials. The specification provides no guidance for distinguishing between a sample of saliva and a sample that comprises both saliva and skin oil. According to the guidance at Table I, these samples would yield identical results in the claimed method.

As discussed above, applicants present a narrow working embodiment in which the emission profiles for a few vaguely defined biological materials are presented (Table I). While a singular, narrow working embodiment cannot be a sole factor in determining enablement, its limited showing, in light of the unpredictable nature of the art and the direction applicants present, provides additional weight to the lack of enablement in consideration of the *Wands* factors as a whole. Thus, one of ordinary skill in the art would not have a reasonable expectation of success in using the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites "a method for the detection and **differentiation** of biological materials", which is confusing. The term "differentiation" has two distinct definitions in the art: the process of distinguishing one sample from another, and the process by which progenitor cells undergo genetic and physical changes to become specific cell types. Clarification is required. In the interest of compact prosecution, the term "differentiation" has been interpreted in accordance with the first definition above. The examiner suggests that the preamble of claim 1 be redrafted to recite "distinguishing" instead of "differentiation."

Claim 1 recites the limitation "said intrinsic fluorophore in the biological material" in line 4. There is insufficient antecedent basis for this limitation in the claim. Claim 1

does not recite an intrinsic fluorophore in the biological material *per se*. Clarification is required.

Claim 1 recites the limitation "the signal intensities" at line 6. There is insufficient antecedent basis for this limitation in the claim. Claim 1 does not recite signal intensities before line 6. In addition, line 6 describes the signal intensities as being "associated with" the minima and maxima of the intrinsic fluorescence, but does not point out the manner of said association. Clarification is required.

Claim 1 recites the limitation "the background intensities" at line 8. There is insufficient antecedent basis for this limitation in the claim. Claim 1 does not recite background intensities before line 8. Clarification is required.

Claim 1 recites the limitation "the intensities of the reflectance and scattering" and "the background-subtracted minima" at lines 10 and 11, respectively. There is insufficient antecedent basis for this limitation in the claim. Claim 1 does not recite intensities of the reflectance and scattering or background-subtracted minima before lines 10 and 11. In addition, claim 1 recites "an appropriate algorithm" at line 12, but does not point out what characteristics an algorithm must possess to be considered "appropriate" for the claimed method. Clarification is required.

Finally, claim 1 is confusing in that it is drawn in part to a method for the differentiation (*i.e.* distinguishing) of biological material, but none of the steps appear to give such a result. It is not clear that the recited steps yield the result claimed in the preamble. Clarification is required.

Because claims 2 and 3 depend from indefinite claim 1 and do not clarify all of the above points of confusion, they must also be rejected under 35 U.S.C. 112, second paragraph.

Claim 2 uses passive language in lines 3 and 6 ("...are determined"). The claim should be amended to recite active process steps. Clarification is required.

Claim 2 is further confusing in that it recites "the differentiation between the biological material" but does not point out from what comparator the biological material should be differentiated, *i.e.*, distinguished. Clarification is required.

Claim 2 is further confusing in that it recites that the differentiation "depends on" a requirement, but it is not clear how the differentiation depends on said requirement. Clarification is required.

Claim 2 is further confusing in that it recites "the requirement that the ratios of the background, scattering, and reflectance-corrected fluorescence signals lie within specified ranges and that the amount of material is determined by the magnitude of said detected signals the ratios of which lie within said expected ranges." There are numerous problems with these lines. First, the examiner suspects that "requirement" at line 4 should read "requirements", since there appear to be two requirements. Second, the claim recites "reflectance-corrected fluorescence signals", "said detected signals", and "said expected ranges", but there is insufficient antecedent basis for these limitations in the claim. The claim does not point out the manner in which the magnitude of the detected light is used to determine the amount of material. Finally, the examiner

suspects that a comma should be inserted after the word "ratios" at line 7. Clarification is required.

Claim 3 is confusing in that it requires that the intrinsic fluorescence be selected from a list of ranges; it is not clear whether these ranges refer to the excitation wavelengths or the emission wavelengths. Clarification is required.

Claim 3 is in improper Markush form; the claim should recite, "said biological intrinsic fluorescence is selected from the group consisting of 320-360nm, 380-460, 430-380", and so on. Currently, it is not clear which species are included in the Markush group and which are not.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 2 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 16, and 17 of U.S. Patent No. 6,750,006, which is currently commonly owned and shares two inventors with the instant application. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the claims in the '006 patent is completely encompassed by the scope of the instant claims.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); and *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Instant claims 1 and 2 are generic to all that is recited in claims 1-7 and 16-19 of the '006 patent. That is, the scope of claims 1-7 and 16-19 of the '006 patent falls entirely within the scope of instant claims 1 and 2 or, in other words, instant claims 1 and 2 are anticipated by claims 1-7 and 16-19 of the '006 patent. Specifically, the instant claims are drawn to a method for detecting biological material comprising exciting an intrinsic fluorophore; the cited claims of the '006 patent are drawn to a method for detecting microbes, a particular type of biological material, comprising exciting an intrinsic fluorophore. The dependent claims of the '006 patent more particularly point out the type of microbe (for example, claims 4 and 5) and the nature of

the fluorophore (for example, claims 3 and 6). The instant claims encompass all biological materials and all fluorophores and, therefore, encompass all of the claimed embodiments of the '006 patent.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Powers (1998, U.S. Patent 5,760,406; IDS of 4/2/04). The claims are drawn to a method for the detection and distinguishing of biological material comprising exciting at least one intrinsic biological fluorophore with fluorescence excitation wavelength above 200nm; detecting the fluorescence signals, including the maxima and minima of the excited fluorophores; and subtracting the reflected and scattered excitation and background energies from the detected signals, whereby the amount of biological material is determined by the magnitude of the detected fluorescence.

Powers (1998) teaches a method for detecting microbes on a non-living surface comprising exciting NADH within the microbes by irradiating them with light of wavelength 350-390nm (column 3, lines 30-34), detecting the emission signals resulting from the irradiation of NADH, processing the signals (column 4, lines 23-46), and performing numerous calculations (column 5, line 66, through column 6, line 20). The

method of Powers is a method for distinguishing microbes growing on meat or poultry from the cells comprising said meat or poultry (column 5, lines 21-41).

Claims 1-3 are also rejected under 35 U.S.C. 102(b) as being anticipated by Powers (1999, U.S. Patent 5,968,766; IDS of 4/2/04). The claims are drawn to a method as described above.

Powers (1999) has a disclosure essentially identical to that of Powers (1998), especially with respect to the passages cited above.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Ho (1997, U.S. Patent 5,701,012; IDS of 4/2/04). The claims are drawn to a method as described above.

Ho teaches a method for detecting living microbes in a stream of air comprising exciting NADH and riboflavin within the microbes by irradiating them with a 320-360nm ultraviolet laser (column 3, lines 60-63), detecting the emission signals resulting from said irradiation (column 3, lines 64-67), subtracting background signals (Example III), removing scattered light (column 6, lines 55-62), and performing numerous calculations (column 4, lines 1-12) of the particles' size and biological viability. The method of Ho is a method for distinguishing airborne microbes from inert dust (column 3, lines 1-4).

No claims are allowed. No claims are free of the art.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be

applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lora E. Barnhart whose telephone number is 571-272-1928. The examiner can normally be reached on Monday-Friday, 8:00am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SANDRA E. SAUCIER
PRIMARY EXAMINER

Lora E Barnhart

/lb/